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REMARKS

Claims 1-23 are pending in the application. Claims 9-19 have been withdrawn as being non-elected.

Claims 1-8 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Densert et al (USPN 6,159,171).

Claims 1, 6 and 7 are currently amended. No new claims are added. No new matter is added.

Reconsideration and allowance of all pending claims is requested.

Claim Rejections – 35 U.S.C. § 102

Claims 1-8 and 20-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Densert.

Densert teaches a device that supplies static and modulated pressure levels to the ear of a patient suffering, for example, from Ménière's disease to treat the same. (Column 1, lines 8-11.) Ménierè's disease is defined at www.thefreedictionary.com as "[a] pathological condition of the inner ear characterized by dizziness, ringing in the ears, and progressive loss of hearing." Furthermore, Densert teaches *away from* vestibular function testing, which traditionally involves so-called "caloric" stimuli whereby a cold or warm fluid, e.g. air, is intentionally introduced into a test subject's ear to produce vertigo. (Column 6, lines 18-47 re tightly controlling the temperature of the air so that it is "essentially" at body temperature of +37°C.) So, the focus of the Densert invention is more tightly to control the static air pressure and pressure pulses produced by his device (but not necessarily impacting in a good way on the patient's ear) in an attempt to avoid inducement of transient or sustained negative ear pressures. (Column 6, line 13-17.)

Moreover, Densert teaches nothing whatsoever about vestibular function testing of a test subject. Densert teaches treatment of a patient for a disease adversely affecting the patient's hydro-dynamic inner ear system. Thus, Densert is barely analogous prior art to applicant's claimed invention. Furthermore, Densert's focus is on patient stimulus, not patient response (involving induced static air pressure and pressure pulses delivered to nozzle 25 and, if Densert's nozzle 25 is properly affixed in the patient's ear 32, to the patient's middle ear). For this reason, Densert teaches nothing at all about measuring or monitoring or testing the patient's response to such air pressure stimuli as part of vestibular testing.

Indeed, Densert teaches patient stimulation by the use of "predetermined pressure changes in accordance with a predetermined program controlled by a control unit [29]." (Abstract.) Thus, Densert does not teach feedback and control based upon patient response to stimuli. In fact, if Densert's apparatus were sitting on a desk rather than being properly affixed proximate a patient's ear, it would operate the very same way it is described to operate. This is because Densert fails to measure or monitor the *patient's response* to the ear pressure stimuli. Densert's apparatus can be thought of as one-way treatment, without patient involvement or feedback, whereas the instant invention involves patient-induced response feedback and computer-aided control based thereon and responsive thereto.

To the contrary, Densert teaches only a pressure sensor means 28 and a safety sensor means 30 having nothing to do with the patient's response to the stimuli. (Column 5, lines 37-42, lines 53-59: "The static pressure is registered by the pressure sensing means 28 and is transferred to the control unit 29 which in turn ... interrupts the pumping motion of the static-pressure generating means when a predetermined treatment pressure level is obtained ... Should for some instance the pressure sensor means 28 fail for some reason and a non-desired high pressure build up in the interconnection means, the safety sensor means 30 is arranged to emit the signal to the control unit 29, the latter in turn being arranged to cease the pressure-raising movements of the pistons 15 and 16.") In purpose and effect, Densert teaches only sensing whether his pump and seal are working in accordance with the programmatic design, and does not measure, test or monitor in any way the patient's response to the air pressure stimuli or any other patient vestibular parameters.

This is an important distinction—Densert simply makes *a priori* assumptions about the amplitude and frequency of the static and modulated air pressure and then uses such programmed assumptions, without the benefit of feedback regarding the patient's response thereto, to deliver the prescribed and predefined air pressure 'dose' regardless of what its effect, if any, on the patient. One might call Densert's approach presumptuous patient 'care.'

Claim 1 recites a "*head-wearable frame structure* for wearing on a subject's head *in a condition thereon of relative positional stability.*" Densert fails to even suggest such a frame structure, on or off a subject's head, and fails even remotely to suggest relative positional stability thereon. (The only Densert drawing is largely schematic, i.e. symbolic, rather than physically depictional. Thus ear pressure nozzle 25, pressure sensor means 28, control unit 29, safety sensor means 30, ear 32, etc. all are shown as functional blocks, without structural detail or suggestion and without structural interconnection or mounting or support detail. One of ordinary skill in the art learns nothing from Densert about how to position, assemble,

interconnect, mount, support, manipulate or otherwise employ the array of functional blocks in a real-world application.) Claim 1 further recites "at least a pair of "vestibular-parameter data-parameter devices selectively anchored/anchorable to said frame structure *in conditions thereon of relative positional stability both with respect to the frame structure and with respect to one another.*" Densert fails even remotely to suggest such a structure that meets such conditions. Claim 1 further recites that the devices are adapted to engage in at least one of the activities including delivering to and receiving from the subject's head "vestibular-relevant parameter data." Densert's apparatus is for treatment of Ménière's disease, which does not remotely suggest its use to deliver to or receive from the subject's head any data relevant to vestibular function.

Conspicuously absent from Densert is any reference to or suggestion of a head-wearable frame structure or anchoring structure for anchoring devices of any sort thereto for relative stability thereamong. The Examiner seemingly admits as much, by failing to point out in the Office action where such is suggested to one of ordinary skill in the art, without the benefit of applicant's invention disclosure thereof and claims thereto.

Finally, claim 1 further recites that the communication structure operatively associable with appropriate computing structure is adapted to accommodate at least one of the tasks "including (a) communicating *[the] parameter data* to, and (b) communicating *[the] parameter data* from, [the] devices. Since Densert's concern is treating Ménière's disease instead of testing vestibular function, clearly any Densert "data" communicated in either direction are not vestibular parameter data.

To make this last one of many distinctions over Densert even clearer, applicant hereby amends claim 1 to expressly recite that it is "the vestibular-relevant parameter data" that are delivered to and received from the subject's head that are communicated by the communication structure to an associable computing structure. Applicant submits that claim 1, as amended, is clearly allowable over Densert's Ménière's disease treatment teachings.

Regarding claim 6 as originally filed, applicant submits that it is allowable because it depends from allowable claim 1. Furthermore, Densert fails to teach any tympanic membrane-piercing member or fluid delivery therethrough. Densert's only teachings are of a nozzle piece 25 inserted into the auditory tube of the patient's ear 32, "e.g. via a tube in the tympanic membrane." (Column 5, lines 19-22; Fig. 2.) This auditory tube is understood by those of ordinary skill in the art to refer to an anatomical feature of the patient that tends to equalize air pressure between the patient's middle ear behind the tympanic membrane and the patient's external ear canal in front of the tympanic membrane. Thus, Densert teaches neither

"piercing" of the tympanic membrane nor any structure "configured to pierce" the tympanic membrane. Densert relies instead on the natural anatomical feature of mammals referred to as the "auditory tube" that extends through the tympanic membrane to deliver his controlled static pressure and pressure pulses to the patient's middle ear. Clearly, where there is a naturally occurring tube for air pressure conveyance, i.e. a natural conduit for such air pressure transmission, there is no taught need or means to configure any kind of tympanic membrane piercing structure for air or other fluid, e.g. drug, delivery to the middle or inner ear, as is claimed by applicant. As a consequence, Densert teaches no such mechanism for piercing a patient's or subject's tympanic membrane.

Applicant hereby amends claim 6 to better define his invention as involving "tubular fluid-flow body structure having an end configured to pierce the tympanic membrane."

The Examiner seems to rely in rejecting claim 6 not only on what Densert teaches, but also on what is "inherent" in Densert's disclosure. Applicant submits that, considering that Densert relies on a naturally occurring anatomical tube to deliver his static air pressure and pressure pulses, there is no sustainable inherency argument. This is especially so in consideration of applicants' amendment to claim 6 more clearly and definitely claiming a feature of the fluid-flow structure that includes a tubular fluid-flow body structure having an end specifically "configured to pierce" the tympanic membrane of the test subject. Thus, even if Densert's nozzle piece 25 is capable under accidental or deliberate force of piercing the patient's tympanic membrane—by misuse thereof against its intended purpose, which is very simply to convey static and pulsed air to the patient's outer ear canal—it is not "configured" for that purpose or effect.

Accordingly, applicant submits that amended claim 6 is allowable over the known prior art.

Claim 7 also is amended hereby more definitely to describe applicant's invention. Specifically, amended claim 7 now properly recites the plural nature of data. Suffice it to say that Densert fails to teach "computing structure including algorithm structure which equips the computing structure to perform substantially real-time operations relative to such delivered and received, different-parameter data, *including performing the operation of vestibular-disorder correlation and analysis of received data.*" (Emphasis added.) Indeed, Densert teaches away from vestibular disorder correlation and analysis performance by a computing structure, as pointed out above with respect to claims 1 et seq. Moreover, Densert teaches nothing about "computing structure ... adapted to share in the delivery *and reception of such different-parameter data [which are relevant to diagnosis and treatment of a*

vestibular disorder] with those devices." (Emphasis added.) As pointed out above, Densert delivers and receives only equipment performance data, not vestibular disorder-relevant different-parameter data. Accordingly, applicant submits that claim 7, along with claim 8 depending therefrom and reciting further limitations, is allowable.

Claim 20 recites structure taught nowhere in the prior art references including Densert. Claim 20 includes the following element:

> data-flow and control interposition structure, including feedback structure, operatively interposed said headgear, said computer, the subject, and the attending user, operable, in relation to the expert-trained capabilities of said algorithm structure, (a) to collect data from, and to effect the delivery of stimuli to, the subject via said headgear, and further (b) to effect and control the engagement of selected diagnosing and treating activities with respect to the subject, including initiating such effecting and controlling *as a feedback response to such collected data*.

(Emphasis added.) Densert does not teach collecting "subject" data (as is pointed out above with respect to claims 1 et seq) and certainly does not teach effecting control of the engagement of selected diagnostic "and" treatment activities relative to the subject *by initiating such effecting and controlling as a feedback response to such collected data*. In other words, Densert teaches nothing about feedback effect and control based upon collected subject data of a feedback structure that is a part of data-flow and control interposition structure operatively interposed headgear, computer, subject and attending user.

Applicant submits that claim 20, as originally filed, along with claims 21-23 dependent therefrom and further limiting thereof, is allowable.

All claims thus being allowable, as amended and/or argued, reconsideration and allowance is respectfully solicited.

Accordingly, applicant requests entry of the above amendments and reconsideration of the application on its merits. The Examiner is encouraged to telephone the undersigned at (503) 984-2824 if it appears that an interview would be helpful in advancing the case.

Respectfully submitted,

James G. Stewart
Reg. No. 32,496
Ater Wynne LLP
222 SW Columbia, Suite 1800
Portland, Oregon 97201

I hereby certify that this correspondence is being transmitted to the U.S. Patent and Trademark Office via facsimile number (571) 273-8300 on August 17, 2006.

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